Doing It Right

NDMAC believes that timeliness, quality of the analysis, proportionality of analysis to impact, quality of consultation in communication, consistency and predictability, coverage of the system; and accountability are some of the criteria by which to measure the success of the regulatory management system.

However, we believe there are also a number of other criteria that should come into play which could improve the regulatory management system. They are as follows:

Risk Management

This concept should be used in the approach to regulation. Risk management involves assessing and managing risks to public health to ensure they are minimized to the extent possible and practicable. Risk assessment determines the nature and degree of risk, based on scientific evidence. This approach is an important way to manage issues and decisions in an environment of scarce resources and competing demands. We recommend risk management be included as a criteria.

Performance Measurement

In the area of performance measurement, a more rigorous process for setting and reporting on regulatory performance is needed. To improve the regulatory process, the government could introduce requirements to establish operational performance targets for each of its operational units in Business Plan(s), include operational targets in the department's Report on Plans and Priorities and report on the effectiveness of achieving these targets in the annual Departmental Performance Report. We recommend performance measurement be included as a criteria.

Decision-Making Authority

In circumstances where regulations involve technical or scientific decisions, such as product approvals, authority should be delegated to senior technical experts to ensure that the decisions are fact-based and not overly influenced either by political or administrative issues. It is our understanding that many Ministers regard day-to-day approval decisions as "too technical" and something that could be performed by officials, notwithstanding the fact that the Ministers are often questioned in the House of Commons about the decision reached, although this is a rare occurrence. This would also allow the Minister to focus on broader public policy objectives. We recommend that for technical and scientific decisions that criteria for regulatory success be the delegation of authority to senior technical experts.

International Cooperation

The globalization of business make the harmonization of processes and sharing of information inevitable, although there remains concerns regarding giving up the right to make decisions. However, Canada should seek opportunities for developing Memorandum of Understanding or Mutual Recognition Agreements with other countries. Canada is a participant to several Mutual Recognition Agreements (MRAs) covering drug/medicinal products Good Manufacturing Practices (GMP) Compliance Programmes.

The Mutual Recognition Agreement approach is an effective way to enhance international regulatory cooperation and maintain high standards of product safety and quality while facilitating the reduction of the regulatory burden for industries. International cooperation and information sharing appears to be critical to regulatory efficiency and success.

Getting the Regulatory Policy Right

The Government of Canada Regulatory Policy is concise, but to meet the needs of today should be revised to encompass new thinking and smart regulation. As a cultural change will probably be needed for regulators to become more enabling, a good starting point would be a revision of the current Regulatory Policy.

Although the current policy requires justification that "regulation is the best alternative", there is no direction on alternate means of addressing a problem or risk. The Regulatory Policy should make it clear that regulation should be the final option chosen and that regulators should first seek out alternatives, such as voluntary programs, codes of practices, technical directions, etc.

The Regulatory Policy omits any mention of risk management, which should be a strong consideration when considering regulatory activity. The consideration of risk management principles should be added to the Policy requirements section and expanded upon and further explained in the Regulatory Process Management Standards (Appendix B).

The Policy should also ensure that the effect of regulation on the capacity to innovate and the competitiveness of Canadian companies in relation to those of major trading partners are considered. This is an especially important consideration if regulation is the only option.

Appendix B of the current Policy includes a section on policy development and analysis. These are process oriented and should be expanded to discuss methodologies that could be used to meet the standards.

The Policy omits consideration of the monitoring of compliance and enforcement. As these activities could be resource intensive, this should be considered early in the process. We have also noted that review/monitoring of the policy once implemented has not been included. This is also an important facet of regulations and should be compulsory for all new regulations.

Defining the Problem

It is important for the government to involve stakeholders in a working group in the early stages to help identify and define problems or risks. The government should initially identify those stakeholders that would be most affected by the problem or those that have either prior experience and/or knowledge pertinent to the issue. The working group could

then work in an agenda-setting role, as well as draft a problem definition statement and develop some possible alternatives to address the problem or risk. Results from these initial discussions could then be taken to public consultation with a broader range of stakeholders. This would ensure that those most affected would be consulted early in the process, as well as ensure that all other interested stakeholders are fully consulted in the final problem definition phase and alternatives selection phase.

Should any stakeholder contest the government's view on the problems and/or the need for action, then an appropriate dispute resolution procedure could be used. We would suggest that an independent "Regulatory Ombudsman" should be established and serve as a coordinator.

Assessing and Communicating Risk

Health Canada's Health Products and Food Branch has established the Office of Consumer and Public Involvement to provide opportunities for Canadians, especially users of the products regulated by the Branch, to become meaningfully involved in the decision-making processes regarding priorities, policies and programs. NDMAC believes this model could be enhanced and used in other departments to engage the public in regulatory activities.

Best Solutions

Policy makers should always consider alternative approaches to problems or risks and regulatory action should only be considered should all other options be ineffective. However, for this to succeed, there needs to be a cultural shift in government away from implementing restrictive regulations. There may be alternative means of addressing problems or risks without regulations. Regulations typically impose a burden on industry, thereby affecting competitiveness and consuming scarce government resources in terms of ongoing monitoring, compliance and enforcement activities.

Stakeholders that will be affected by the problem should be permitted to meet with government officials to discuss appropriate alternatives to regulation. All approaches should be considered and presented to a multi-stakeholder group before a decision has been reached. Although regulators will deny that alternatives have been chosen prior to multi-stakeholder workshops, there have been instances where it appears that an option has been selected and the multi-stakeholder workshop is more for garnering support rather than consultation and feedback.

Should regulation be the only option that can address a problem or risk, then the regulator should be required to justify the decision. Should the decision be opposed, an appropriate dispute resolution procedure could be used. An independent "Regulatory Ombudsman" should be established and serve as a coordinator.

Cost-Benefit Analysis

Equally important to a cost-benefit analysis is cost-effectiveness, which should be conducted on all major regulatory initiatives to assess their impact, among other factors, on trade, competitiveness and innovation.

Different types of analysis may require different types of methodologies. Although developing common assumptions and methodologies may be difficult initially, as experience is developed, common methodologies may emerge.

Improving the Analysis

Impact analysis can be handled in two stages. We suggest that government initially convene working groups of stakeholders most likely to be affected early in the process. There may be non-regulatory alternatives that address the problem or risk. The second stage would present the draft problem definition statement and possible alternatives for action to a multi-stakeholder group.

To ensure that the problem or risk is adequately defined, we would support the requirement to prepare an impact analysis much earlier in the process. This would lead to better information and opportunities to seek alternatives to regulation.

Monitoring should be a requirement for all regulations following implementation to ensure the solution to the problem or risk has been successful. All too often regulations may be implemented that do adequately address the problem or risk. This leaves industry having to comply with regulation that is not optimal and may have a detrimental effect on competitiveness and innovation.

Improving the Information for Stakeholders and Decision-Makers

Most of the Regulatory Analysis Impact Statements for regulatory proposals developed by the Health Products and Food Branch that we review are informative and provide suitable background information, as well as Branch responses to stakeholder comments. However, we believe sections on cost-benefit analysis and cost-effectiveness can be improved, especially for major initiatives. We suggest that all departments develop groups that can develop socioeconomic data for RIASs.

NDMAC is a science-based organization and believes that information in the RIAS must also be science-based and supportable. Sometimes this requires the document to be technical in nature. While we do not oppose the development of non-technical summaries, this should not detract from providing science-based information.

Although we regularly review *Canada Gazette* Parts I and II, these publications should be made more easily accessible to stakeholders through departmental web sites.

An area that is sometimes lacking in the RIAS is a references section with instructions or links to supporting documents. This would enable stakeholders to further consider the statements contained in the RIAS and lead to more informed citizens.

The RIAS is currently subject to the contesting of assumptions, scientific studies and conclusions when it is published in *Canada Gazette* Part I. A monitoring of the regulations after implementation would help ensure the regulation is accomplishing its objectives and permit new information to be considered and the regulation to be revised, should it be required.

Improving Transparency and Openness

The comprehension of regulations could be improved through the use of plain language. Although the government announced an intention to use plain language in regulations between 5 and 10 years ago, it did not occur to any great extent. For this to work top down support is required and the lawyers who draft regulatory text must use plain language.

Another means to improve the comprehension of regulations is to release guidelines that explain how the regulations will be applied and/or interpreted at the same time as the regulations are implemented. This will help clarify expectations for all stakeholders and clarify legal obligations.

All regulations and their associated guidelines must be posted on departmental web sites and search engines must be improved. Departments may wish to consider licensing commercial search engines.

Improving Communication

The government frequently seeks feedback from stakeholders on a broad range of issues. Consultation documents should contain more concise summaries and enough background to provide context. There must also be sufficient time allowed for feedback to allow stakeholders to consult with their constituents.

There is also a need for a predictable process. There is sometimes a one to two year interval between consultations on the same subject. This leads to a loss of continuity by both government and stakeholders; reduced motivation and can lead to a cynical view of the entire consultative process. If the issue is identified as a priority, then resources should be allocated accordingly and the issue should be completed within proposed time frames.

Consultation schedules should be established and published early in the process and should also include the level of priority, anticipated time lines and key contacts. Should the schedule not be kept, regulators should be accountable and provide valid reasons for missing targets.

Advisory bodies should only be sought for significant issues where greater depth of knowledge and/or experience would be expected to contribute solutions to a problem or risk. Advisory bodies may be useful in areas where unbiased scientific expertise, not generally available to government or other stakeholders, would be beneficial.

Regulatory Impact Analysis Statements from departments with which we have experience generally adequately address concerns expressed in consultation that is not addressed through regulation. However, should a non-regulatory option to address a risk or problem be chosen, an analysis document should be prepared to explain the decision to all stakeholders.

Ensuring Fair and Effective Administration of Regulation

A critical factor in regulatory policy should be a "level playing field" approach. For example, products of similar risk making health claims should be regulated in a similar manner, including having similar standards of evidence requirements as well as similar good manufacturing practices requirements.

If a regulation is enacted, then departments should have the resources in place to monitor compliance with the policy and take enforcement activities when necessary. Those not complying with a regulatory requirement should receive similar treatment with a similar outcome.

There may be alternative approaches to achieve compliance. The government must be flexible and allow stakeholders to meet compliance expectations through different approaches. A "best practices" approach might be to develop regulations that are less prescriptive with a more flexible framework that would allow stakeholders to meet expectation by the most cost-effective means.

In general, the government does not do a good job communicating its enforcement activities and outcomes. We suggest that compliance divisions produce semi-annual reports of their compliance activities, including investigations launched and the outcomes of the investigations. The independent advertising preclearance agencies, Advertising Standards Canada and the Pharmaceutical Advertising Advisory Board publish a list of investigations initiated and the outcomes. These are distributed to many stakeholders and are made available on their web sites.

Government can be more creative with regulatory administration and enforcement. Although some stakeholders continue to call for a "Made in Canada" approach, we should not be out of step with our major trading partners. We must not impose unique regulations that either constitute a trade barrier and/or affect the competitiveness of Canadian companies.

The Regulation We Have

There are many regulations that are out of step with developments in our major trading partners and therefore adversely affect the competitiveness of Canadian industry. Revising regulations is an option, but regulatory amendments are resource intensive and generally take a long time to become effective. However, the process may be able to be improved in two areas. When there is multi-stakeholder agreement on regulatory change, it should receive top priority by government with requirements that a regulation would be developed and/or revised and passed within six months.

For science-based decisions, an alternate consultative and administrative process, under Ministerial authority, must be put in place instead of the time-consuming, non-value added *Canada Gazette* Parts II process and I.

The best opportunity to bring regulations up-to-date is when new legislation is introduced. Resources must be in place to develop regulations consistent with the new legislative framework. All legislation should incorporate a regular review period to ensure that legislation and regulation is effective and encourages innovation in Canadian industry.

We believe that all regulatory proposals should include plans for future review, assessment and performance measurement. The review should include assessment of alternative approaches and compliance/enforcement reporting.

Government requires a more formal mechanism to receive comments on regulation. As suggested earlier, a “Regulatory Ombudsman” should be established and charged to fulfill this function.

We have suggested previously that a working group be convened early in the process when a problem or risk has been identified. It might be best to involve members of the working group in the review of the regulation, as this group will have the most knowledge and experience.

Recommendations for Smart Regulation

There are great opportunities to improve the regulatory process, to make it more responsive to the Canadian public and to minimize the impact on Canadian industry in terms of innovation and competitiveness.

Smart Regulation must make it clear that regulation should be the final option chosen and that government should first seek out alternatives. Policy makers should incorporate risk management principles and consider regulatory action only if all other options would be ineffective.

Smart Regulation should establish a process to involve affected stakeholders in a working group in the early stages to help identify and define problems or risks. The working group could then develop an agenda, a draft problem definition statement and some possible alternatives to address the problem or risk. Results from these initial discussions could then be taken to public consultation to ensure that other stakeholders are fully consulted.

Should any stakeholder contest the government's view on the problems and/or the need for action, then an appropriate dispute resolution procedure could be used, coordinated by a “Regulatory Ombudsman”. This Regulatory Ombudsman could also be a more formal mechanism to receive comments on regulation once the External Advisory Committee on Smart Regulation has fulfilled its mandate.

Smart Regulation should require that all regulatory proposals include plans for future review, assessment and performance measurement. The review should include assessment of whether the regulation has been successful in achieving its goal and regular compliance and enforcement reporting.

Smart Regulation has the opportunity to shift government away from implementing restrictive regulations. This would benefit all Canadians.